iDiamond Blood Glucose Monitoring System Owner's Manual Version 1.0 2012-04

System Owner: Thank you for purchasing the iDiamond Blood Glucose Monitoring System. This manual

Dear iDiamond

provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully. Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. Due to its compact size and

easy operation, you can use the iDiamond Blood Glucose Monitoring System to easily monitor your blood glucose levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact the place of purchase or call the Customer Care Line.

Use this device ONLY for the intended use

Do NOT use accessories which are not specified by the manufacturer Do NOT use the device if it is not working properly or if it is damaged.

described in this manual.

IMPORTANT SAFETY PRECAUTIONS READ BEFORE USE

- Do NOT use the equipment in places where aerosol sprays are being used or where
- oxygen is being administered. Do NOT under any circumstances use the 5.
- device on newborns or infants. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only. 6.
- Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control
- checks as directed. Keep the device and testing equipment away from young children. Small items such as the
- battery cover, batteries, test strips, lancets and vial caps are choking hazards. Use of this instrument in a dry environment, especially if synthetic material are present
- (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results 10.Do NOT use this instrument in close proximity to sources of strong electromagnetic
- radiation, as these may interfere with the accurate operation. KEEP THESE INSTRUCTIONS IN A
- SAFE PLACE Contents

Getting Started About the iDiamond Blood Glucose Monitoring System

How to Install and Update the iDiamond Diabetes Manger App Important Health-related Information Intended Use

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Test Principle

Test Strip

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 - Reviewing Record List
- Reviewing Logbook Reviewing Trend Graph
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- **Getting Started**
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- **Glucose Monitoring System** Dock Connector
- Test Strip Slot

Absorbent Hole Apply a drop of blood here. The blood will be automatically absorbed. **Confirmation Window** This is where you confirm if enough blood has been applied to the absorbent hole in the strip. Test Strip Handle Hold this part to insert the test strip into the slot

strip into the meter. Pusit in firmly until it will go no further. NOTE:

ATTENTION: The front side of test strip

Test Strip

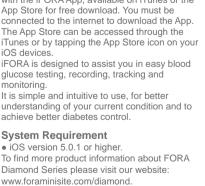
The iDiamond monitor should only be used with iDiamond Test Strips. Using other test strips with this meter can produce inaccurate results

Insert this end of the test

should face up when inserting test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot How to Install and Update the

iFORA Diabetes Manager App

iDiamond is designed to be used in conjunction with the iFORA App, available on iTunes or the



symptoms

iOS devices.

monitoring. simple

Updating

System Requirement iOS version 5.0.1 or higher



may cause readings which are lower than actual values. If you believe you are suffering actual values. from severe dehydration, consult a healthcar professional immediately.

usual,

professional.

of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional. Use only fresh whole blood samples to test your blood glucose. Using other substances will lead to incorrect results.

If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all the instructions given in this owner's manual, contact your healthcare

 If your blood glucose results are lower or higher and you do not have any

 We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a

hyperglycaemic-hyperosmolar state, with or

- ketosis. Please consult the healthcare professional before use. The measurement unit used for indicating the concentration of blood or plasma glucose can either have a weight dimension (mg/dL) or a
- molarity (mmol/L). The approximate calculation rule for conversion of mg/dL in mmol/L is: mg/dL Divided by 18 = mmol/L
- Times 18 mmol/L =mg/dL For example; 1) 120 mg/dL ÷ 18 = 6.6 mmol/L 2) 7.2 mmol/L x 18 = 129 mg/dL approximately.

Intended Use

This system is intended for use outside the body s system is interiored for doc carrier vitro diagnostic use) by people with diabetes nome and by health care professionals in at home and by health clinical setting as an aid to monitoring the effectiveness of diabetes control. It is intended to quantitative measurement of used for the glucose (sugar) in fresh whole blood samples (from the finger, palm, forearm, upper arm, calf and thigh). It should not be used for the diagnosis of diabetes, or testing on newborns.

Professionals may test with capillary and veno blood sample; home use is limited to capillary whole blood testing. Venous blood must be collected only in heparin blood collection tube.

Test Principle

Your system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample. Important Information about Performing Control Solution Tests

ur Control Solution contains a known amount glucose that reacts with test strips and is used to ensure your meter and test strips are working together correctly.

Test strips, control solutions, or sterile lancets may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand. Do a control solution test when:

you first receive the meter, at least once a week to routinely check the meter and test strips,
you begin using a new vial of test strips, you suspect the meter or test strips are not working properly, your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate,

practicing the testing process, or you have dropped or think you may have damaged the meter.

- **How to Perform a Control Solution Test**
- You will need:

Meter

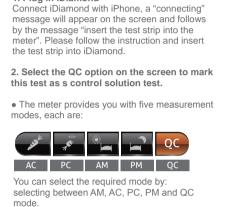
Test Strip Control Solution





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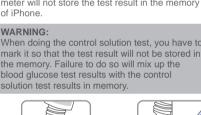
1. Plug in iDiamond



P . .







Apply Control Solution

out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down. To avoid contaminating the control solution, do not directly apply control solution onto a strip.

4. Read and Compare the Result

mg/dL =6.1-9.2 mmol/L)

Shake the control solution vial thoroughly before

Squeeze out a drop and wipe it off, then squeeze

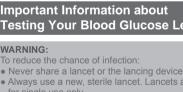
X

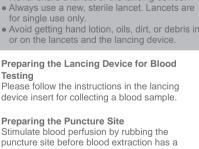
use

After "Processing" message appears, the control solution test result will then show on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test. An example: (117mg/dL = 6.5 mmol/L; 109-165

Normal

Out-of-range results If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood. Contact the local customer service or place of purchase for help NOTE: The control solution range printed on the test strip vial is for control solution use only. It is not recommended range for your blood glucose See the Caring for Your iDiamond Meter Set section for important information about your control solutions.





obtained Blood from a site that has not been rubbed

exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced

significant influence on the glucose value

another body parts (please see section "Obtaining a Blood Sample from Alternative Sites" (AST) on how to select the appropriate sites).
Clean the puncture site using cotton

Rub the puncture site for about 20 seconds before penetration. Use a clear cap (included in the kit) while

Please follow the suggestions below before obtaining a drop of blood:Wash and dry your hands before starting. Select the puncture site either at fingertips or

Fingertip testing

setting up the lancing device.

button to prick your finger, then a click indicates that the puncture is complete. Blood from sites other than the fingertip

Press the lancing device's tip firmly against the lower side of your fingertip. Press the release



NOTE: Choose a different spot each time you test Repeated punctures at the same spot may cause soreness and calluses.

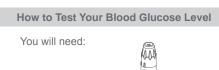
It is recommended that you discard the first drop of blood as it might contain tissue fluid,

which may affect the test result.

health care professional

Please consult your

before you begin AST





Meter

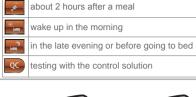
- Test Strip Lancing Device Lancet

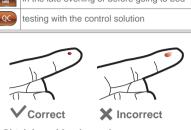


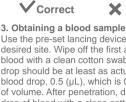
the test strip into iDiamond.

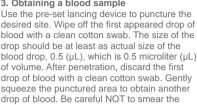
2. Select the appropriate measuring mode by touching the screen. The meter provides you with five measurement modes, each are:

before meal









4. Apply the sample
Gently apply the drop of blood to the absorbent
hole of the test strip at a tilted angle. When the
required amount of blood sample has been
absorbed the confirmation window will be filled*.

blood sample.

Do NOT remove your finger until the "processing" message appears on the screen. Do not press the punctured site against the test strip or try to smear the blood. If you do not apply any blood samples to the test strip within a period, the screen will still keep waiting until any action is taken. The meter will begin to process once the required amount of blood sample has been

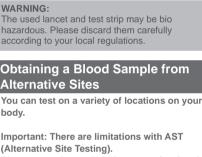
amount of blood sample absorbed. ** If you have not successfully filled the test strip with enough blood samples, the syster will appear with an error message. Please discard the used test strip and retest with a

Read Your Result

- IEVER try to add more blood samples to the
- test strip after the blood absorption process has been completed. Discard the used test strip and retest with a new one
- If you are experiencing trouble with filling the confirmation window, please contact your health care professional or the local customer service for more assistance
- The result of your blood glucose test will appear after the meter shows the "Processing" message. The blood glucose result will be stored in the memory automatically.
- An example: (68 mg/dL = 3.8 mmol/L)



WARNING:



Please consult your health care professional before you perform AST.

When to use AST?

Do NOT use AST if:

Menu.

medication,

Food,

body.



can affect blood glucose levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Thus, when testing

illness, stress and exercise

You think your blood glucose is low. You are unaware of hypoglycemia You are testing for hyperglycemia Your AST results do not match the way you feel. Your routine glucose results often fluctuate.

Viewing Past Test Results on iPhone **Data Navigation Guide** Navigate between different functions simply by

selecting the desired function from the Floating





Data Record—by swiping left or right Swipe up to see the next function—Record List





Logbook—by swiping left or right of the log you can switch between current 7 days of glucose testing data to the previous weekly log records. Swipe up to see the next function- Trend Graph 30 Davs K Z



Swipe up to see the next function- Pie Chart

Trend Graph—select the enlarge button on the top right corner to switch between 7-14-30days view.
To see different times, simply slide to the left or right.



until a test has been taken.

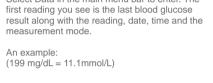


of

Blood Glucose Test Result Result AC – PC AM - PM Blood glucose unit Help To add notes Delete notes Note displays

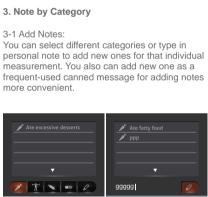
1. Select the Data Record mode from the Main

Menu Bar.



Select Data in the main menu bar to enter. The





Ate a larger portion

QWERTYUIOP Ate excessive desserts Mede carb calculated





Record Titles

Reviewing Record List

| | 2012/03/04 07:38 PM | 124 mg/dL | |
|------------------|---------------------|-----------|-------|
| | 2012/03/03 05:23 AM | 106 mg/dL | |
| | 2012/03/03 07:42 PM | 131 mg/dL | |
| | 2012/03/03 09:29 PM | 117 mg/dL | |
| | 2012/03/02 05:24 AM | 99 mg/dL | |
| | 2012/03/02 07:24 PM | 126 mg/dL | |
| Page Indications | | | |
| | Data/Tervi | Changes | 56050 |
| | | | |

1.Select the Record List mode from the Floating Menu. Select Record List in the Floating Menu to enter. You will see the recent individual measurement

data, and you can switch to all Record List from different times by swiping left or right.



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2.Click at any data record to find out more

Detailed information will pop up with a

information

semi-transparent window.







Menu. Select Logbook in the Floating Menu to enter. The first page you see is the current 7 days of



1.Select the Logbook mode from the Floating

glucose testing data under the measurement 4

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option, then it will show individual trend grapl Also you can select 2, 3 or 4 options to show individual trend graph at the same time.

1.Select the Trend Graph mode from the

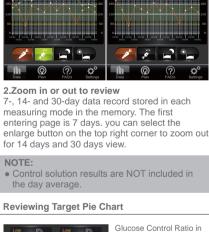
Select Trend Graph in Floating Menu to enter. The first page you will see is the 7-day data The first page you will see is the 7-day data record of the blood glucose test results under the measuring modes. If you select a particular

individual trend graph.

Floating Menu.

four





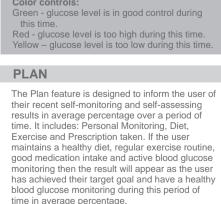
Percentage

Percentage display Current 7-, 14-, 30-Day

Page Indications Select the Target Pie Chart mode from the

Floating Menu. Select Target Pie Chart in Floating Menu to enter. You will see the current 7-day of glucose control ratio in percentage under 4 measuring modes. You can see the percentage in 3 duration times of current 7-14-30-days; to quickly switch





time in average percentage.

Color controls:

NOTE: Do not make treatment decisions based solely Do not make treatment decisions based solely on the information provided by the iFORAApp. All health-related decisions should be made in conjunction with the advice of a qualified healthcare provider (HCP). The plan only acts as reference information for the user's own necessity and to acknowledge their monitoring condition over a certain period of time.



Current Plan 1.Select Plan on the Main Menu Bar to see your Current Plan. If you have already set up a plan before, the firs page you will see is the total overall percentage of personal monitoring achievement during this the first

period.

2.You can set up your plan target and duration period when you first enter the Plan Mode. The setting page will appear when you first enter the Plan Mode. You can set up your desired period and glucose target after consulting your

doctor. t New Plan tion Jun 13, 2012 ~ Jun 19, 2012

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Diary Management

1.8 Bar.

FAQ Medicine, Diabetes 101 and Tutorial

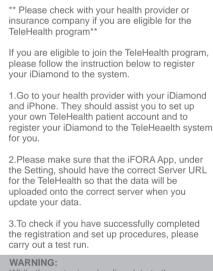
Medicine



• Medicine njectic

ଉ **SETTING**

you are eligible for the



Uploading Results onto TeleHealth System

While the meter is uploading data to the TeleHealth, it will be unable to perform a blood glucose test.

Error Messages and Troubleshooting

MESSAGE

customer service. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances. Result Readings

If you follow the recommended action but the problem persists, or error messages other that

below appear, please call your local

messages other than

WHAT IT MEANS

Reading in yellow when glucose is low.

Reading in red when glucose is high

contact the

custome

to Repeat the

test after

the meter

strip are in the above temperature range. Repeat with

a new test

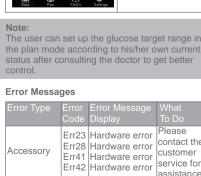
strip.

Please contact the

and test

| Data | (A) Plan | (F |
|------|-------------|--------|

Reading in green when glucose is normal.



service for Hardware error assistance. Temperature System Err25 is too low operation range is 10°C to 40°C (50°F to 104°F).

Temperature

Strip has been

used

is too high

Strip

exhausted.

Test strip inserted

Defective meter or test strips.

upside down or incompletely.

Err26

Err24

Temperature

| | Err30 | of range | customer service for assistance. | | | |
|--|-------|---|--|--|--|--|
| Measurement | Err40 | Strip is removed during measurement | Repeat the test with a new test strip. | | | |
| | Err45 | Insufficient blood sample | | | | |
| Troubleshooting 1. If the meter does not display a message after inserting a test strip: | | | | | | |
| POSSIBLE CAUSE | | WHAT TO DO | | | | |
| Battery of iPhone | | Recharge the hattery of iPhone | | | | |

Insert the test strip with contact

Please contact customer services.

bars end first and facing up.

Repeat the test using a new test strip with larger volume of blood sample. sample. Repeat the test with a new test Defective test strip. strip. Sample applied Repeat the test with a new test strip after automatic Apply sample only when flashing" switch-off appears on the display. Defective meter. Please contact customer services. If the control solution testing result is out of range. POSSIBLE CAUSE | WHAT TO DO Error in performing Read instructions thoroughly and the test. repeat the test again. Shake the control solution Control solution vial vigorously and repeat the test again as poorly shaken.

2. If the test does not start after applying the

POSSIBLE CAUSE WHAT TO DO

sample:

Ехрі red or

contaminated

Fasting and before meal 2 hours

after meals

control solution.

Insufficient blood

Defective test strip. new test strip. Please contact customer services Meter malfunction. Reference Plasma Glucose Range

Check the expiry

control solution

date of the

Control solution, meter, and test strips should be at room temperature 20°C to 25°C (68°F to 77°F) before testing.

Repeat the test with a Control solution that is too warm or too cold. The meter provides you with plasma equivalent results. Time of day Normal plasma glucose range for people without diabetes (mg/dL)

Source:

<100 mg/dL (5.6 mmol/L)

< 140 mg/dL (7.8 mmol/L)

American Diabetes Association (2010). Clinical Practice Recommendations. Diabetes Care, 33 (Supplement 1): S1–S100.
Please consult your doctor to determine a target Please

range that works best for you. Caring for Your iDiamond Meter Set

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

Cleaning

To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT rinse with water. 2. Do NOT use organic solvents to clean the

meter Meter Storage Storage conditions: -20°C to 60°C (-4' to140°F), below 95% relative humidity
 Always store or transport the meter in original storage case. -20°C to 60°C (-4°F

Avoid dropping and heavy impact.
Avoid direct sunlight and high humidity.

Caring for Your Test Strips

Storage conditions: 2°C to 32°C (35.6°F to 89.6°F), below 85% relative humidity. Do NOT freeze.

Store your test strips in their original vial only. Do not transfer to another container. container. Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.

• After removing a test strip from the

vial

- immediately close the vial cap tightly.

 Touch the test strip with clean and dry hands.

 Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first opened it. Discard remaining test strips after 3 months.
 Do not use test strips beyond the expiry date. This may cause inaccurate results. Do not bend, cut, or alter a test strip in any
- way. Keep the strip vial away from children since the
- cap and the test strip may be a choking hazard.

 If swallowed, promptly see a doctor for help. r further information, please refer to the test
- strip package insert Important Control Solution Information

 • Use only our control solutions with your meter.

 • Do not use the control solution beyond the
- meter. expiry date or 3 months after first opening.
 Write the opening date on the control solution
- vial and discard the remaining solution after 3 months It is recommended that the control solution test
- be done at room temperature 20°C to 25°C (68°F to77°F). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
 Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser
- tip to ensure a pure sample and an accurate result.
 Store the control solution tightly closed at temperatures between 2°C to 30°C (36°F to 86°F). Do NOT freeze.
- iDiamond Meter Specifications

Model No.: DM40

mm,

IVD

(2)

ш SN

nm, 13.6 g ower Source: iPhone Memory: Control by iPhone External output: Apple 30 pins Connector Auto electrode insertion detection

Dimension & Weight: 55 (L) x 36 (W) x 12.10 (H)

- Auto sample loading detection Auto reaction time count-down
 Auto switch-off after 3 minutes without action Temperature Warning
- Operating Condition: 10°C to 40°C (50°F to 104°F), below 85% R.H. (non-condensing) Storage/Transportation Conditions: -20°C to 60°C (-4°F to 140°F), below 95% R.H. Measurement Units: Control by iPhone Measurement Range: 20 to 600mg/dL (1.1 to 33.3mmg/l)
- 33.3mmol/L) This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, IEC/EN 61326-2-6.

Symbol Referent

Do not reuse

In vitro diagnostic medical device

 \prod_{i} Consult instructions for use * Keep away from sunlight Keep dry Temperature limitation 1 Use by/ Expiry date Use within 3 months after 3M first opening Batch code LOT

Manufacturer

Serial number

documents

Caution, consult accompanying

STERILE R Sterilized using irradiation (B) Do not use if package is damaged Authorized representative in the European Community EC REP **C** €₀₄₅₉ CE mark